

HEALTH AND SENIOR SERVICES

HEALTH CARE QUALITY AND OVERSIGHT BRANCH

HEALTH CARE QUALITY AND OVERSIGHT DIVISION

ACUTE CARE FACILITY OVERSIGHT

CERTIFICATE OF NEED AND ACUTE CARE LICENSURE PROGRAM

Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers

Proposed Readoption with Amendments: N.J.A.C. 8:33E

Authorized By: Fred M. Jacobs, M.D., J.D., Commissioner,
Department of Health and Senior Services (with the
approval of the Health Care Administration Board).

Calendar Reference: See Summary below for explanation of
exception to calendar requirement.

Authority: N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5.

Proposal Number: PRN 2006-1

Submit comments by March 4, 2006 to:

John A. Calabria, Director

Certificate of Need and Acute Care Licensure Program

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes the readoption with amendments N.J.A.C. 8:33E, Certificate of Need; Cardiac Diagnostic Facilities and Cardiac Surgery Centers, which, pursuant to N.J.S.A. 52:14B-5.1, and Executive Order No. 66(1978), is scheduled to expire on January 18, 2006. In accordance with N.J.S.A. 52:14B-5.1c, the filing of this notice of proposal with the Office of Administrative Law prior to January 18, 2006, operates to extend the expiration date of N.J.A.C. 8:33E to July 17, 2006. The Department has reviewed N.J.A.C. 8:33E and has determined that the rules remain necessary, adequate, reasonable, efficient, understandable and responsive to the purposes for which they were promulgated. Establishing these minimum requirements resulted in a high level of quality care for cardiac patients. The readoption of these rules with amendments would continue to serve that end.

The Department has continually recognized the importance of maintaining Statewide cardiac care policy that assures the provision of high quality cardiac

services that are accessible and affordable to all New Jersey residents. For the past three decades, administrative rules for the full range of diagnostic and therapeutic cardiac services have been established and amended periodically by the Department, often with the assistance of ad hoc and/or standing technical advisory committees consisting of prominent State and national cardiac experts.

The Department is proposing the readoption with amendments of the certificate of need and licensing standards for cardiac services, N.J.A.C. 8:33E, to update and revise these cardiac standards for all licensed general and special hospitals. The Department intends to consolidate all of the cardiac service licensing rules, some of which are contained in this chapter, in the cardiac subchapter of the Hospital Licensing Standards N.J.A.C. 8:43G, at a future date. The proposed amendments include the following:

1. The Department proposes to replace references in the definition sections of the chapter (N.J.A.C. 8:33E-1.2 and 2.2) and throughout the entire chapter, in order to reflect current clinical terminology, the term “percutaneous transluminal coronary angioplasty” (PTCA) with references to the term “percutaneous coronary intervention” (PCI).
2. The Department proposes to amend N.J.A.C. 8:33E-1.6(d)2 to delete the prohibition against use of a confidence interval to evaluate an overall low-risk cardiac catheterization laboratory’s performance with respect to the 25 percent maximum normal study rate. Since the minimum facility volume requirement was previously reduced (that is, from 350 cases per year to 200) through amendment of this paragraph

(see 36 N.J.R. 416(a)), the application of a confidence interval in the evaluation of relatively low volume facilities is an appropriate statistical evaluative measure.

3. The Department proposes new N.J.A.C. 8:33E-1.13(b)1ii, to indicate that minimum annual cardiac catheterization volume requirements for physicians would be enforced during the Department's annual licensing evaluation process only for directors of cardiac catheterization laboratories at this time pending the development of an outcomes-based evaluative system.
4. The Department proposes to amend N.J.A.C. 8:33E-2.3(a)3 to provide an alternative approach to the evaluation of low- volume physician performance that is consistent with the alternative approach set forth for the evaluation of low- volume cardiac surgery centers (N.J.A.C. 8:33E-2.3(a)2) The proposed new N.J.A.C. 8:33E-2.3(a)3 permits physicians performing less than the required 100 open heart surgery cases per calendar year to be evaluated based on an alternative approach that considers the physician's performance of isolated coronary artery bypass graft surgery (CABG) over the previous four years that the physician has performed CABG cases in New Jersey and compares that physician's risk-adjusted mortality rate with that of the most recent published Statewide observed isolated CABG mortality rate. In the event that the physician has not been operating in New Jersey for four years, the review will include all isolated CABG cases

performed in a New Jersey cardiac surgery center. If the physician's risk adjusted mortality rate is less than or equal to the most recent published Statewide observed isolated CABG mortality rate through the use of this alternative methodology, then the physician is to be considered in compliance with the minimum annual physician volume requirement. If the audit results in a higher physician risk-adjusted mortality rate than the most recent published Statewide observed isolated CABG mortality rate, the facility shall be licensed conditionally and the provision of N.J.A.C. 8:33E-2.13(a) shall apply.

5. The Department proposes new N.J.A.C. 8:33E-2.3(d)4iii, to indicate that minimum annual physician volume standards for percutaneous coronary interventions would be enforced during the Department's annual licensing evaluation process only for cardiac catheterization laboratories licensed to perform primary or emergency PCI as set forth at N.J.A.C. 8:33E-2.16(b)6.
6. The Department proposes to amend N.J.A.C. 8:33E-2.4(e)1ii and (f)1ii to reflect changes in the board certification policy of the American Board of Internal Medicine (ABIM) with respect to board certification in cardiology. Since 1990, the ABIM has placed a 10-year limit on its certification in cardiology, thereby requiring cardiologists to be recertified every 10 years. In addition, the ABIM no longer requires the maintenance of internal medicine certification in order to achieve recertification in the cardiology subspecialty and no longer uses the

term “board-eligible.” The proposed amendment would reflect current ABIM certification policy by deleting the term “board-eligible.”

7. The Department proposes to amend N.J.A.C. 8:33E-2.16(b)1 to delete the requirement of collaboration by a primary PCI catheterization laboratory with a cardiac surgery center that is located in the same municipality as a potential primary angioplasty provider. The Department no longer considers it necessary, so long as the requirement for timely (that is, within one hour) transfer of patients to the collaborative New Jersey cardiac surgery center, as required at N.J.A.C. 8:33E-2.16(b)1i, is met.
8. The Department is amending the definition of "PCI" at N.J.A.C. 8:33E-1.2 to be consistent with the "PCI" definition set forth at N.J.A.C. 8:33E-2.2. This amendment would provide a consistent and clinically accurate definition of PCI throughout the chapter.

The cardiac services certificate of need rules proposed for readoption with the above amendments address the full range of invasive cardiac diagnostic and therapeutic services provided in licensed general and special hospitals. Following is a summary of the rules proposed for readoption as proposed for amendment as described above:

Subchapter 1 establishes the certificate of need requirements for invasive cardiac diagnostic services. N.J.A.C. 8:33E-1.1 sets forth the scope and purpose

of the subchapter. N.J.A.C. 8:33E-1.2 sets forth definitions of words and terms used throughout the subchapter, including terms that differentiate low-risk and full-service cardiac catheterization facilities. N.J.A.C. 8:33E-1.3 sets forth the general criteria for invasive cardiac diagnostic facilities, including: the settings for the provision of these services (subsection (a)); the requirement that cardiac catheterization services be performed in a hospital-based facility where inpatient services are available on-site (subsection (b)); the requirement that pediatric cardiac catheterization services be performed in a hospital that also provides pediatric cardiac surgery (subsection (c)); and the requirement that complex electrophysiology, elective PCI and primary PCI services be performed in a cardiac surgery center (subsection (d)), unless a certificate of need has been granted for that purpose.

N.J.A.C. 8:33E-1.4 sets forth the minimum utilization standards for all invasive cardiac diagnostic facilities and physicians, which are based on the number of patients upon whom invasive cardiac diagnostic procedures were performed (subsection (a)). Minimum annual facility and physician volume standards are established for full-service cardiac catheterization facilities (subsection (b)) and low-risk cardiac catheterization facilities (subsection (c)).

N.J.A.C. 8:33E-1.5 sets forth the minimum personnel requirements for the performance of invasive cardiac diagnostic services. N.J.A.C. 8:33E-1.6 sets forth the requirements for a quality improvement program that includes the maintenance of a peer review mechanism to evaluate the invasive cardiac diagnostic facilities performance. At a minimum, the peer review mechanism is

required to evaluate criteria such as overall case selection, laboratory and physician performance and study quality (subsection (a)). The criteria that are selected must be based on sound medical practice (subsection (b)), with each peer review team containing at least one cardiovascular surgeon from the surgical center to which the facility's surgical candidates are commonly referred by their (patients') physicians (subsection (c)). Minimum quality of care outcome measures are also set forth in subsections (d) and (e).

N.J.A.C. 8:33E-1.7 sets forth community outreach, access and prevention standards that require invasive cardiac diagnostic facilities to maintain appropriate mechanisms to assure access to services and to promote cardiac health among underserved populations in their respective service areas (subsection (a)). At a minimum, hospitals are required to document their annual community prevention services, develop a plan designed to ensure appropriate access to their respective programs by medically underserved and minorities and also document the proportion of Medicaid-eligible and medically underserved groups residing in the service area (N.J.A.C. 8:33E-1.7(a)1 through 3).

N.J.A.C. 8:33E-1.8 sets forth the requirement that invasive cardiac diagnostic facilities that do not provide cardiac surgery on-site develop and maintain written agreements with a cardiac surgery center to ensure, among other things, rapid patient referral, emergency backup and transport and regular communication between the cardiologists performing the cardiac diagnostic procedure and the surgeons to whom the patients are referred. These written referral agreements should also minimize duplication of services by having the

receiving facility, to the extent possible, accept the results of the diagnostic facility's examinations (subsection (b)).

N.J.A.C. 8:33E-1.9 requires invasive cardiac diagnostic facilities to maintain and provide statistical patient-level data on the operation of the catheterization laboratory and report those data to the Department on a quarterly basis and in a standardized format determined by the Department.

N.J.A.C. 8:33E-1.10 requires invasive cardiac diagnostic facilities to maintain current written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients.

N.J.A.C. 8:33E-1.11 sets forth the criteria for the submission of certificates of need (CN) for full-service invasive cardiac diagnostic services. These criteria include the submission of an expedited review CN application that addresses the eligibility and application review criteria set forth at N.J.A.C. 8:33E-1.15 (subsection (a)) and N.J.A.C. 8:33E-1.3 through 1.10 (subsection (b)). Applicants are also required to comply (subsection (c)) with the general CN statutory criteria (N.J.S.A. 26:2H-1 et seq.), the CN application and processing rules (N.J.A.C. 8:33) and the cardiac services licensing rules (N.J.A.C. 8:43G). Finally, a Board Resolution acknowledging and accepting the standards and criteria contained in this subchapter as conditions of approval and licensure is also required (subsection (d)).

N.J.A.C. 8:33E-1.12 is reserved.

N.J.A.C. 8:33E-1.13 sets forth the requirements for licensure of invasive cardiac diagnostic facilities, with services initially licensed annually in accordance

with cardiac service licensing requirements as set forth at N.J.A.C. 8:43G (subsection (a)). Annual license renewal of invasive cardiac diagnostic facilities is only to be granted upon documentation of full compliance with all applicable standards and criteria of this chapter, N.J.A.C. 8:43G and 8:33, N.J.S.A. 26:2H-1 et seq., any applicable Federal law and any conditions imposed upon the license holder by the Department upon original CN approval (subsection (b)). Upon receipt of license renewal documentation, the Department shall review and evaluate the documentation, communicate with the facility if necessary, and communicate a renewal decision in a timely manner (subsection (c)). License renewals are to be valid for one year and the failure of an existing invasive cardiac diagnostic facility to document compliance with annual license renewal criteria will require the provider to submit to an external review from an independent external organization approved by the Department and to submit a detailed plan of correction within 30 days of notification of noncompliance (subsection (d)). Failure to comply with the provisions of a corrective action plan will result in revocation of the license for the service unless an appeal for a hearing is filed with the Commissioner within 60 days of receiving the notice of revocation (N.J.A.C. 8:33E-1.13(d)3). The licensure requirements in this section are also in addition to and not in limitation of any other applicable authorities not specifically mentioned in the section and from which the facility in question has not been exempted by law (subsection (e)).

N.J.A.C. 8:33E-1.14 sets forth the role of the Commissioner's cardiovascular health advisory panel (CHAP) to provide the Commissioner with

expert clinical or technical advice for the development of sound cardiovascular health policy.

N.J.A.C. 8:33E-1.15 sets forth the requirements for the submission of CN applications to provide full-service invasive cardiac diagnostic services. CN applications that are in compliance with the eligibility requirements are to be accepted on a monthly basis and processed on an expedited review basis (subsection (a)). CN applicants are also required to document compliance with the applicable standards and criteria of this subchapter (subsection (b)). Finally, except where specifically exempted or superseded, the compliance of all CN applicants to the requirements in this subchapter is in addition to and not in limitation of any other applicable CN provisions of this subchapter, N.J.S.A. 26:2H-1 et seq., N.J.A.C. 8:33 and N.J.A.C. 8:43G (subsection (c)).

Subchapter 2 contains the standards and criteria pertaining to the services provided by regional cardiac surgery centers, or, in the case of primary PCI, non-cardiac surgery center hospitals providing primary PCI. N.J.A.C. 8:33E-2.1 sets forth the scope and purpose of the subchapter, which establishes the standards and criteria for the establishment of a regional cardiac surgery center.

N.J.A.C. 8:33E-2.2 sets forth definitions of words and terms used throughout the subchapter, including “cardiac surgery center,” “complex electrophysiology study,” “inner city cardiac satellite demonstration project,” “percutaneous coronary intervention” (PCI) and “stent procedure.”

N.J.A.C. 8:33E-2.3 sets forth the utilization standards and criteria that include facility and physician minimum annual volume requirements for: new and

existing adult (subsection (a)) and pediatric (subsection (b)) cardiac surgery services; invasive cardiac diagnostic services located within a cardiac surgery center (subsection (c)); PCI (subsection (d)); and complex electrophysiology studies (subsection (e)).

N.J.A.C. 8:33E-2.4 sets forth the minimum personnel requirements, including minimum education, training and experience requirements, for: new and existing adult cardiac surgery services (subsection (a)); intensive care cardiac recovery room (subsection (b)); invasive cardiac diagnostic services located within a cardiac surgery center (subsections (c) and (d)); PCI services (subsection (e)); and complex electrophysiology studies (subsection (f)).

N.J.A.C. 8:33E-2.5 sets forth the inpatient capabilities that are required to support the minimum annual cardiac surgery volume of 350 cases. At a minimum, an intensive care unit with four beds must be provided with capabilities that include: hemodynamic ECG monitoring; temporary pacemaker insertion; resuscitative equipment and supplies (including defibrillator and cardiac emergency medications); and cardiac assist devices (such as an intra-aortic balloon pump).

N.J.A.C. 8:33E-2.6 is reserved.

N.J.A.C. 8:33E-2.7 sets forth the regional responsibilities for cardiac surgery centers. These responsibilities include: written transfer agreements to receive appropriate cardiac patients from surrounding hospitals (subsection (a)); distribution of a mailing to all appropriate institutions and physicians in the service area announcing the availability of cardiac surgery services (subsection

(b)); and written documentation of an institutional policy statement, that is reviewed annually, stating that the cardiac surgery center will accept the referral of patients from physicians not ordinarily having access to the facility (subsection (c)).

N.J.A.C. 8:33E-2.8 is reserved.

N.J.A.C. 8:33E-2.9 requires full written documentation of the implementation and operating costs of the certificate of need project for the establishment of a cardiac surgery center.

N.J.A.C. 8:33E-2.10 sets forth the requirement for the maintenance and provision of patient characteristic and outcome data, in a standardized format determined by the Department, and submitted on a quarterly basis to the Department. If necessary to determine compliance with this chapter, the Department may require the data submitted to be audited at the hospital's expense by an independent third party approved by the Department.

N.J.A.C. 8:33E-2.11 requires every cardiac surgery applicant to maintain a current written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients.

N.J.A.C. 8:33E-2.12 sets forth the standards and criteria for a quality improvement program, including appropriate mechanisms for peer review (subsection (a)). The selected criteria are required to be based on sound medical practice and consistent with the literature (subsection (b)). In addition, all cardiac surgery centers are to participate in a continuous quality improvement program

that meets nationally-recognized standards of improvement in cardiovascular care (subsection (c)).

N.J.A.C. 8:33E-2.13 sets forth the licensing compliance requirements for pediatric and adult cardiac surgery centers. Annual license renewal of pediatric or adult cardiac surgery centers is only to be granted upon documentation of full compliance with all applicable standards and criteria of this chapter. Compliance with minimum annual volume requirements is to be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date (subsection (a)). License renewals are to be valid for one year and the failure of an existing pediatric or adult cardiac surgery center to document compliance with annual license renewal criteria will require the provider to submit to an external review from an independent external organization approved by the Department (paragraph (a)1) and to submit a detailed plan of correction within 30 days of notification of non-compliance (paragraph (a) 2). Failure to comply with the provisions of a corrective action plan will result in revocation of the license for the service unless an appeal for a hearing is filed with the Commissioner within 60 days of receiving the notice of revocation (paragraph (a)3). All CN applicants must document compliance with the minimum standards and criteria set forth in this subchapter in accordance with the petition and CN submission criteria (N.J.A.C. 8:33E-2.14) and the competitive CN review criteria (N.J.A.C. 8:33E-2.15), as applicable (subsection (b)). All CN approved applicants for pediatric and adult cardiac surgery centers shall have two years from the date of CN approval to initiate services through the licensing process. Failure to do so will result in

the automatic termination of the CN, unless the Commissioner determines that the failure was the result of unforeseen circumstances beyond the control of the applicant (subsection (c)).

N.J.A.C. 8:33E-2.14 sets forth the petition process, which describes the Department's processing of CN applicants for cardiac surgery services from general hospitals after a hospital has petitioned the Department and established the potential unmet need for new cardiac surgery services and the petitioner is qualified to meet the potential unmet need. The minimum standards for the petition process are set forth at N.J.A.C. 8:33E-2.14(a)1. The schedule, timeframe and fee for the petition process are set forth at N.J.A.C. 8:33E-2.14(a)2. The status of a petitioner that is unsuccessful in establishing the potential need for new cardiac surgery services is set forth at N.J.A.C. 8:33E-2.14(a)3. Finally, N.J.A.C. 8:33E-2.14(a)4 requires the Commissioner, in the event of a successful petition, to issue a regional call for the submission of certificate of need applications for new cardiac surgery services within 60 days of the petition decision. This paragraph also sets forth the required contents of the call, including submission timeframes, the opportunity for affected facilities to obtain copies of the applications and the opportunity for the written submissions by affected facilities in response to the applications.

N.J.A.C. 8:33E-2.15 sets forth the competitive review criteria for the certificate of need process for new cardiac surgery programs. Subsection (a) states that the goal for considering new cardiac surgery programs is to improve access to all cardiac services, especially to the minority and medically

underserved populations while at the same time assuring the quality of services. Subsection (b) states that consideration of approval will be limited to the applicant(s) that meets the competitive review criteria in this subsection and all other criteria in the subchapter and statute (N.J.S.A. 26:2H-8) to a greater extent than the competing applicants.

N.J.A.C. 8:33E-2.16 sets forth the criteria for the submission of a certificate of need application for the provision of PCI in emergent situations with off-site cardiac surgery back-up. Subsection (a) states that the goal for considering the provision of PCI without the availability of on-site cardiac surgery is to promote wider access to appropriate emergency PCI services while assuring the quality of services. Expedited review applications for emergency or primary PCI services are to be accepted on the first business day of the month.

Subsection (b) sets forth the specific criteria that shall be addressed by each certificate of need applicant in order to obtain certificate of need approval for emergency or primary angioplasty services.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

N.J.S.A. 26:2H-1 et seq., as amended, recognizes as "public policy of the State that hospitals and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost

are of vital concern to the public health.”

During the past decade, New Jersey's healthcare delivery system has experienced rapid change. With the deregulation in the early 1990s of hospital rates and increasing market-based competition, the Department recognizes the need to use its certificate of need and licensing standards to promote within a market-driven system both quality of care and access to health care services, including invasive diagnostic and therapeutic cardiac services for all New Jersey residents. Particular emphasis is given to those population groups that have historically been underrepresented in accessing these services (for example, minority and medically underserved populations). The cardiac literature continues to reflect a strong correlation between higher facility and physician volume and lower mortality rates, reinforcing the need to promote a distribution of cardiac services that maintains adequate volumes. Additionally, the Department's extensive cardiac data collected from existing centers have confirmed the relationship between volume and quality. The Department's enforcement of minimum volume requirements, as set forth in this chapter, has contributed to a continuous decline in Statewide observed mortality for coronary artery bypass surgery. In 2002, for example, the Statewide operative mortality rate for coronary artery bypass surgery was 2.15 percent, representing an improvement of 14 percent from the previous year and 53 percent since 1994. In the area of cardiac surgery, where volumes Statewide have declined in recent years, the Department also uses risk-adjusted mortality rates to assess the performance of low volume providers, since the volume-quality correlation is not perfect. The

proposed amendments would extend this assessment approach to low volume surgeons as well. In this way, access to care may be maintained in regions of the State with existing low volume providers who have demonstrated high quality.

Historically, regionalization of specialty services and equipment is widely viewed as an important means of assuring high quality of care by generating caseloads of sufficient volume to maintain professional skills, thereby reducing unnecessary risks to patients while promoting efficient and effective delivery of these services. Regionalization of such services is currently accomplished in New Jersey largely through the certificate of need process, by which the State principally controls the number and locations of providers who will be permitted to initiate them. Hence, the Department now proposes to readopt these rules to retain existing Statewide policy, while continuing to engage in dialogue with stakeholders and interested parties regarding the future oversight of hospital-based cardiac care services in New Jersey, particularly with respect to the updating of the standards for complex electrophysiology studies and annual physician volume requirements and/or other physician performance measures that can be developed.

The Department's amendments are largely intended to provide public evaluative mechanisms for facility and physician performance that recognize that the volume-quality relationship is not perfect and that outcomes-based evaluative systems could be developed to assure the provision of quality services. With respect to the proposed amendment that permits the use of a confidence interval for the review of a cardiac catheterization facility's percentage of normal studies,

the amendment represents an effort to assure that the evaluation process that is used is statistically valid, particularly with respect to the evaluation of facilities that provide improved access to quality services despite relatively low annual case volume. The proposed amendment that provides an alternative approach to the evaluation of relatively low volume cardiac surgeon performance is consistent with the approach that is currently used for low volume cardiac surgery centers and relies on actual patient outcomes as opposed to strict reliance on a surrogate quality measure (that is, annual volume). Similarly, the proposed amendment to enforce individual physician volume requirements only on cardiac catheterization laboratory directors at this time is based on the recognition that an alternative, outcomes-based, evaluation process is being developed. Finally, the Department no longer considers it necessary for a primary angioplasty provider to collaborate with a cardiac surgery center in the same municipality, since there is already a requirement for the timely transfer of patients, (that is, within one hour) to a collaborative New Jersey cardiac surgery center. In each case, the Department's proposed amendments recognize the need to maintain appropriate oversight of the State's cardiac services in order to ensure high quality cardiac services are available and accessible to the public.

Economic Impact

The standards contained in this chapter establish minimum utilization, staffing and professional credentialing, and reporting requirements that are designed to promote high quality invasive cardiac diagnostic services,

therapeutic cardiac intervention services, and open heart surgery services by assuring appropriate volume levels to maintain professional skills and provide efficient and effective service. The Department assumes that providers would incur most of these costs, absent these rules, since the standards are the minimum necessary to offer cardiac programs of sufficient quality. There are recordkeeping and reporting costs associated with reporting patient-level data to the Department. The Department has been advised these cost \$100,000 per hospital, but has no independent means of verifying this cost. No additional costs to providers or consumers of cardiac services are anticipated as a result of this proposed readoption with amendments, since the majority of the requirements are currently in force. All proposed amendments would have a positive economic impact if they have any impact at all, since they would make it easier to comply.

Federal Standards Statement

There is currently no Federal standards or requirements applicable to the rules proposed for readoption with amendments, therefore, a Federal standards analysis is not required.

Jobs Impact

Implementation of the rules proposed for readoption and the proposed amendments would have no impact on jobs, since the they would neither create nor reduce jobs. There are currently a limited number of cardiac catheterization providers and cardiac surgery centers that have been granted certificate of need approval under this chapter. This number of providers is not expected to change

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

significantly under the rules proposed for readoption with amendments.

Agriculture Industry Impact

The rules proposed for readoption and the proposed amendments would not have any impact on the agriculture industry.

Regulatory Flexibility Statement

The rules proposed for readoption and the proposed amendments are applicable only to hospitals, which employ well over 100 employees. Thus, they are not small businesses as that term is defined in N.J.S.A. 52:14B-15 et seq., and no regulatory flexibility analysis is necessary.

Smart Growth Impact

The rules proposed for readoption and the proposed amendments would have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:33E.

Full text of the proposed amendments follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

SUBCHAPTER 1. CARDIAC DIAGNOSTIC FACILITIES

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

8:33E-1.1 Scope and purpose

(a) The purpose of this subchapter is to establish standards and general criteria for the planning of cardiac diagnostic facilities and for the preparation of an application for a certificate of need for such a facility. The invasive cardiac diagnostic facility specializes in the detection and diagnosis of cardiac disorders. Unlike the cardiac surgery center in which both diagnostic and therapeutic services are co-located, the invasive cardiac diagnostic facility does not provide cardiac surgery or [PTCA] percutaneous coronary intervention (PCI) but rather on the basis of diagnostic studies refers patients, where appropriate, to facilities offering cardiac surgery and other advanced cardiac diagnostic and treatment modalities. To increase access to these services, low risk cardiac catheterization programs have been established that are subject to facility performance standards contained at N.J.A.C. 8:33E-1.4(c) and 1.14 intended to ensure the continual delivery of safe patient care, efficiently and effectively provided.

1. (No change.)

(b) – (d) (No change.)

8:33E-1.2 Definitions

For the purposes of this subchapter, the following definitions shall apply: .

. .

"Cardiac surgery center" refers to a facility capable of providing invasive diagnostic catheterization, and all treatment modalities including open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG)

surgery, [PTCA] PCI, and complex EPS studies.

. . .

“Percutaneous [transluminal coronary angioplasty (PTCA) or balloon angioplasty] coronary intervention (PCI)” means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, [PTCA] PCI also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures [)].

. . .

8:33E-1.3 General criteria for invasive cardiac diagnostic facilities

(a) - (c) (No change.)

(d) Complex electrophysiology studies (EPS) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing complex EPS shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E-2.3(e). Elective [PTCA] PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent during acute myocardial infarction) [PTCA] PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

8:33E-1.6 Quality Improvement

(a) – (c) (No change.)

(d) All facilities applying to provide or providing a low-risk cardiac catheterization facility or a full service adult diagnostic cardiac catheterization facility shall also provide written documentation that the proposed services shall adhere to the following quality of care outcome measures:

1. (No change.)

2. A physician-specific and overall low-risk laboratory percentage of normal studies that does not exceed 25 percent of total annual cardiac catheterization cases calculated [without] with the application of a confidence interval;

3.-5. (No change.)

(e) (No change.)

8:33E-1.13 Requirements for licensure of certificate of need approved invasive cardiac diagnostic facilities

(a) All facilities seeking to initiate invasive cardiac diagnostic services pursuant to an approved certificate of need shall be initially licensed on an annual basis in accordance with the provisions of N.J.A.C. 8:43G.

(b) Licenses for facilities referenced in (a) above may be renewed on an annual basis only upon a demonstration by the license holder to the satisfaction of the Commissioner, of full compliance with all applicable standards and criteria

of this chapter, N.J.A.C. 8:43G; N.J.A.C. 8:33; N.J.S.A-26:2H-1 et seq.; any applicable Federal law; and any additional conditions imposed upon the license holder in the original certificate of need approval.

1. All facilities seeking renewal of licenses issued pursuant to the full service or low risk cardiac catheterization facility described in this subchapter shall submit to the Department of Health and Senior Services, documentation of their full compliance with all standards and criteria referenced in (b) above, specifically including, but not limited to, the verified utilization criteria pursuant to N.J.A.C. 8:33E-1.4(b) and 1.9 for full service cardiac catheterization facilities and independently audited and verified utilization criteria pursuant to N.J.A.C 8:33E-1.4(c) and 1.9(a)1 for low risk cardiac catheterization facilities. Where applicable, plans of correction must be submitted indicating what licensure renewal criteria are deficient, what corrective actions are to be put in place or what systemic changes will be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance.

i. (No change.)

ii. The Department will not consider in its annual licensing evaluation the annual volume of physicians with hospital privileges to perform diagnostic cardiac catheterization with the exception of annual laboratory director volumes set forth at N J A C 8:33E-1.4(b)2.

(c) – (e) (No change.)

SUBCHAPTER 2. REGIONAL CARDIAC SURGERY CENTERS

8:33E-2.1 Scope and purpose

(a) (No change.)

(b) A regional cardiac surgical center is defined as a health care facility which specializes in most aspects of cardiac service, including at a minimum cardiovascular surgical services as well as invasive cardiac diagnostic and therapeutic catheterization (for example, [PTCA] PCI, complex EPS) services. With the exception of an inner city cardiac satellite demonstration project as specified at N.J.A.C. 8:33-3.11(c), these cardiac surgery services are to be provided at a single hospital location.

(c) – (e) (No change.)

(f) The cardiovascular surgical services include open heart, closed heart and coronary artery surgery; surgery of the great vessels; and implantation of cardiac assist devices, such as the intra-aortic balloon pump. Therapeutic catheterization procedures include [PTCA] PCI. The requirements contained in this subchapter for facilities, personnel and equipment for open heart surgery shall be the minimum requirements for all cardiovascular surgical and interventional cardiology procedures.

8:33E-2.2 Definitions

For the purposes of this subchapter, the following definitions shall apply: .

..

"Cardiac surgery center" refers to a facility capable of providing invasive diagnostic catheterization, and all invasive therapeutic cardiac services including

open and closed heart surgical procedures. This includes: coronary artery bypass graft (CABG) surgery, [PTCA] PCI and complex EPS studies.

“Complex [Electrophysiology Study] electrophysiology study” (EPS) refers to the more complex variety of electrophysiology study and includes:

Procedures which intend to induce ventricular or supraventricular tachycardia;

Activation sequence mapping of cardiac tachyarrhythmias;

Electrode Catheter ablative procedures;

Implementation of anti-tachyarrhythmia devices and implantable cardioverter defibrillators.

These complex procedure are in contrast to non-complex electrophysiologic procedures, which primarily involve His-Purkinje conduction evaluation without arrhythmia induction.

...

"Invasive therapeutic cardiac services" means the full array of therapeutic cardiac interventional procedures that includes, but is not limited to, coronary artery bypass graft (CABG) surgery, percutaneous [transluminal] coronary [angioplasty] intervention ([PTCA] PCI), and complex electrophysiology studies (EPS).

...

“Percutaneous [transluminal coronary angioplasty or balloon angioplasty] coronary intervention (PCI)” [PTCA] means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the

balloon to reduce the obstruction. For purposes of these rules, [PTCA] PCI also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

. . .

8:33E-2.3 Utilization of cardiac surgical centers

(a) The following shall apply to adult cardiovascular surgical units:

1.-2. (No change.)

3. Each cardiac surgical center shall establish a minimum caseload per physician in order to ensure a consistent level of proficiency within the surgical program. A minimum of 100 cases per year shall be performed by each cardiac surgeon performing as the primary surgeon on any case. This volume shall be achieved at each licensed site in New Jersey at which the physician practices as primary surgeon on any case.

Compliance with annual physician volume standards will be calculated on a calendar year basis. Physicians that perform fewer than 100 open heart surgical procedures per year shall alternatively achieve a risk-adjusted mortality rate (mortality at discharge) for isolated coronary artery bypass graft (CABG) surgery that is lower than the Statewide observed mortality rate (mortality at discharge) for isolated CABG surgery (the alternative method).

i. Data for calculating a physician's risk-adjusted isolated CABG mortality rate shall be derived from the isolated CABG cases in the Department's open heart database for the most recent four years that the

physician has performed open heart cases. For physicians performing surgery in New Jersey for less than four years, the review shall include all isolated CABG cases performed in a New Jersey cardiac surgery center.

ii. The Statewide observed isolated CABG mortality rate shall be the Statewide rate for the most recent calendar year reported in the Department's most recent published report on cardiac surgery performance.

iii. Calculation of a physician's risk-adjusted mortality rate shall be based on the risk-adjustment model used to create the Department's most recent published report on cardiac surgery performance. However, there shall be no use of a confidence interval in determining how a physician's risk-adjusted mortality rate compares to the Statewide observed mortality rate.

iv. The physician risk-adjusted and Statewide observed mortality rates shall be expressed as a percentage calculated to two decimal places.

v. A physician who demonstrates compliance through the alternative method shall be considered in compliance with the minimum annual physician volume standard and the physician's annual volume will not be considered in the hospital's relicensure evaluation for that year. However, the Department reserves the right to confirm the accuracy of the information relevant to the risk-adjustment calculation submitted by the facility to the Department's open heart database. If the Department's audit adjustments result in a revised physician risk-adjusted mortality rate that is higher than the Statewide observed mortality rate, then the facility shall be licensed conditionally and the provisions of

N.J.A.C. 8:33E-2.13(a) shall apply.

(b) – (c) (No change.)

(d) The following shall apply to adult cardiac surgery centers providing or seeking to provide [percutaneous transluminal coronary angioplasty (PTCA)] PCI services:

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide [PTCA] PCI services in its invasive cardiac diagnostic laboratory must provide written documentation that the center will perform a minimum of 200 [PTCA] PCI procedures per year by the third year of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels for either the program or individual physicians during the third year of operation or thereafter will be required to submit to the process that has been established at (d)2 below.

2. A regional adult cardiac surgery center shall continue to perform a minimum of 200 [PTCA] PCI procedures annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing [PTCA] PCI shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for [PTCA] PCI will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter for either the program or individual physicians will be required to submit to the following:

i.-iii. (No change.)

3. Elective [PTCA] PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent during acute myocardial infarction) [PTCA] PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

4. Each [PTCA] PCI facility shall establish a minimum number of [PTCA] PCI procedures for each physician with [PTCA] PCI laboratory privileges. Each physician performing [PTCA] PCI procedures as the primary operator shall perform a minimum of 75 [PTCA] PCI cases a year. (This minimum caseload may be accomplished at more than one laboratory in or out of State.) The physician's minimum annual patient volume is to be achieved at the end of a three year phase-in period, requiring 50 [PTCA] PCI cases as primary operator during the first (CY 2004) and second year (CY 2005), and 75 [PTCA] PCI cases by the end of the third year (CY 2006) and annually thereafter.

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform [PTCA] PCI; physician not a member of the staff for an entire year; or new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission by the hospital of a written waiver request in accordance with the hospital licensing

waiver provisions as set forth at N.J.A.C. 8:43G-2.8.

ii. (No change.)

iii. The Department will not consider in its annual licensing evaluation the annual volume of physicians with hospital privileges to perform diagnostic cardiac catheterization with the exception of annual laboratory director volumes set forth at N J A C 8:33E-1.4(b)2.

(e) The following shall apply to adult cardiac surgery centers providing or seeking to provide complex electrophysiology studies (EPS):

1-4. (No change.)

8:33E-2.4 Cardiac surgery center personnel

(a) – (d) (No change.)

(e) The following shall apply to invasive cardiac diagnostic facilities located in cardiac surgery centers that seek to perform [percutaneous transluminal coronary angioplasty (PTCA)] PCI:

1. Each invasive diagnostic facility must be staffed, at a minimum, by the following personnel during a [PTCA] PCI procedure:

i. The physician directing the procedure shall be a board certified cardiologist with well-recognized excellence in the management of routine cardiac catheterization and who has participated in a minimum of 100 [PTCA] PCI procedures (with at least 50 as primary operator) and meets the licensing qualifications specified at N.J.A.C. 8:43G-7.29(a);

ii. An assisting physician, if needed, may be a board–

certified [or board-eligible] cardiologist or a cardiology fellow;

iii. A registered nurse meeting the licensing requirements specified at N.J.A.C. 8-43G-7.30(a)2 shall be available to assist with [PTCA] PCI procedures; and

iv. One assistant meeting the licensing requirements specified at N.J.A.C. 8:43G-7.30(a)3 shall be available to assist with [PTCA] PCI procedures.

(f) The following shall apply to invasive cardiac diagnostic services located in cardiac surgery centers that seek to perform complex electrophysiology studies (EPS):

1. Each invasive cardiac diagnostic service shall be staffed, at a minimum, by the following personnel during a complex electrophysiology study.

i. (No change.)

ii. An assisting board-certified [or board-eligible] cardiologist, if needed, shall be present during complex EPS procedures.

iii.-iv. (No change.)

8:33E-2.5 – 2.9 (No change.)

8:33E-2.10 Data to be maintained and reported

(a) Every cardiac facility licensed to provide therapeutic interventional cardiac-procedures that include, but are not limited to, cardiac surgery and [PTCA] PCI or coronary angioplasty services in accordance with this subchapter

shall maintain and provide data on patient characteristics and outcomes, services to medically underserved populations, community outreach, and individual program components as determined by the Department. All hospitals shall report these data to the Department of Health and Senior Services on a quarterly basis and in a standardized format determined by the Department. If necessary to determine whether a facility is in compliance with this chapter, the Department shall require that the data submitted shall be audited at the hospital's expense by an independent third party approved by the Department.

1.-3. (No change.)

8:33E-2.12 Quality Improvement

(a) Quality control is essential for the consistent high quality level of performance required of any medical services. As one means of quality control, appropriate mechanisms for peer review shall be described in each application for designation as a cardiac surgical center. Such mechanisms should include, but not be limited to, the delineation of criteria for the evaluation of:

1.-3. (No change.)

4. Surgical program performance (including case volume, mortality, complication rate, rate of emergency surgery following unsuccessful [PTCA] PCI and reoperations;

(b) – (c) (No change.)

8:33E-2.16 Submission of certificate of need applications for the provision of

[PTCA] PCI in emergent situations with off-site cardiac surgery back-up

(a) The Department's goal in considering applications for provision of [PTCA] PCI without the availability of on-site cardiac surgery in emergent situations is to promote wider access to appropriate emergency [PTCA] PCI services while assuring quality of care to patients with acute myocardial infarction. Certificate of need applications shall be accepted on the first business day of each month and shall follow the expedited review process.

1. (No change.)

(b) The criteria in (b)1 through 11 shall be considered by the Commissioner in determining whether to grant a certificate of need. The Commissioner may also consider additional information provided by an applicant that the Commissioner deems relevant to such determination.

1. The applicant is able to document collaboration with a New Jersey cardiac surgery center located [in the same municipality as the applicant, or, if there is none in the same municipality, with a New Jersey cardiac surgery center located] in the same county or a contiguous county.

The documented collaboration must include at a minimum:

i. Written protocols assuring that patients will be transferred to and received at the cardiac surgery center's operating room within one hour from time of the determination by the primary operator of the need for transfer. Protocols shall include provisions for emergency transport of patients requiring an intra-aortic balloon pump (IABP);

ii. Regular consultation on individual cases, including use of

technology to share case information in a rapid manner; and

iii. Evidence of adequate cardiac surgery on-call back up;

2. The applicant is able to document how case selection for primary [PTCA] PCI will comply rigorously with the criteria identified in (c) below;

3. The applicant is able to document how the general public will be advised of the availability of primary [PTCA] PCI with off-site surgical backup, and of the protocols for transfer; as well as how informed consent will be secured from patients;

4. The applicant is able to document, based on acute myocardial infarction (AMI) cases admitted in the previous two years in which thrombolytic therapy was administered or the patient was transferred to a cardiac surgery center for primary angioplasty, that it will in its second year of operation perform a minimum of 36 primary [PTCA] PCI cases per year. The applicant is able to document that it will maintain this minimum volume in subsequent years. Primary [PTCA] PCI intervention must be performed routinely as the treatment of choice for a large proportion of AMI patients to ensure adequate facility volume.

Detailed policies to ensure effective care paths must be developed;

5. The applicant is able to document that primary [PTCA] PCI will be available 24 hours/day, seven days per week;

6. The applicant is able to document that each operator performing primary [PTCA] PCI is an experienced interventionalist who performed at least 75 [PTCA] PCI cases at a cardiac surgery center in the previous year and continues to do so during his or her tenure at the freestanding [PTCA] PCI site;

7. The applicant is able to document that its technical catheterization laboratory staff have been trained at an interventional laboratory in a cardiac surgery center;

8. The applicant is able to document that the catheterization laboratory will be equipped with resuscitative equipment, an intra-aortic balloon pump (IABP) support, and a broad array of interventional equipment, as well as meeting all equipment standards at N.J.A.C. 8:43G-7.19;

9. The applicant is able to document its ability to recruit a laboratory medical director board-certified in interventional cardiology by the Cardiovascular Subspecialty Board of the American Board of Internal Medicine, as well as a sufficient number of cardiac care unit nurses with training and experience in hemodynamic monitoring and IABP management. Physicians and support staff performing [PTCA] PCI services at the facility shall meet the minimum requirements for the performance of [PTCA] PCI procedures as set forth at N.J.A.C. 8:33E-2.4(e) and N.J.A.C. 8:43G-7.29 and 7.30;

10. The applicant is able to document its ability to perform primary [PTCA] PCI in a timely fashion, i.e. balloon inflation no later than 120 minutes after admission; and

11. The applicant is able to document its ability to conduct on ongoing program of outcomes analysis and formalized periodic case review, as part of a broader quality assessment and error management system.

(c) The provision of primary [PTCA] PCI without the availability of on-site

cardiac surgery shall be limited to patients with acute myocardial infarction (AMI) who present within 12 hours of onset of AMI and who demonstrate hypotension, congestive heart failure, frank cardiogenic shock, or ischemic symptoms (with ST-segment elevations compatible with AMI or an ECG that prevents diagnosis of an AMI) and these symptoms and ECG changes do not resolve with nitroglycerin. Intervention at facilities with off-site surgical back-up should be avoided in hemodynamically stable patients with:

1. Sixty percent or greater stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter;
2. Extremely long or angulated infarct-related lesions with TIMI grade 3 flow;
3. Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease;
4. Infarct-related lesions of small or secondary vessels; or
5. Lesions in other than the infarct artery.

(d) In order to facilitate the Department's review of the safety and effectiveness of facilities offering primary [PTCA] PCI services, the Department will:

1. Consistent with 8:33E-2.10 develop quarterly reporting requirements for facilities performing primary [PTCA] PCI without on-site surgical back-up; and
2. Communicate guidelines concerning the circumstances under

which a licensed cardiac surgery center shall assume reporting responsibility for the outcomes of patients transferred from a facility performing primary [PTCA] PCI without on-site surgical back-up.

(e) Facilities granted a certificate of need to provide primary [PTCA] PCI in emergent situations without on-site cardiac surgery are required to operate in accordance with the provisions of N.J.A.C. 8:33E-2.3(d) as applicable and (b) above, and/or any conditions imposed on its certificate of need as a condition of continued licensure. Compliance with minimum annual facility volume requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Compliance with annual physician volume standards will be calculated on a calendar year basis. Facilities unable to comply with the requirements of this section will be required to submit to the following:

1. – 2. (No change.)

**INFORMATIONAL COPY ONLY. THE NEW JERSEY REGISTER IS THE
OFFICIAL JOURNAL OF STATE AGENCY RULEMAKING**